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Back to the Future – Step back and move forward

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PhUSE SDE, Heidelberg, 10th April 2019


Big banks turn to big data to track clients
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Can You Use Big Data to Track an Elephant Poacher?
Artificial intelligence (AI)
New AI can guess whether you're gay or straight from a photograph
How Artificial Intelligence
form Medicine
AI will not kill us, says Microsoft
How artificial intelligence is shaking up the oil and gas industry

CRO

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Agenda

- Data Standards
- Oncologic Domains
- Next Steps

Data Standards

- Change in data collection process for clinical trials
- Each study with unique set of data, no reusable information across studies
- Creation of processes and metadata inefficient
- Inconsistencies across studies
- Example: Variable gender

Study 1	Study 2	Study 3	Study 4
Variable: GENDER	Variable: SEX	Variable: SEX2	Variable: GEND01
Values: M, F	Values: Male, Female	Values: 1, 2	Values: 0, 1

Data Standards

- Need for standardization
- CDISC is born
- Represents all stakeholders in the pharmaceutical industry
- Development of multiple models

Data Standards

- Advantages of data standards:
  - ✓ Increasing data quality
  - ✓ Reducing design and execution time
  - ✓ No organization-specific dataset formats
  - ✓ Worldwide community
  - ✓ Fewer questions by reviewers
- More products with less cost
- Benefits for all parties

Oncologic Domains

- Initial identification of tumor lesions
- One record per tumor

- Quantitative/qualitative measurements
- Support of response evaluation

- Response evaluation based on TR

CRF: Tumor Identification/Results Target Lesions

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[TUTESTCD = TUMIDENT and TUORRES = TARGET]

Response Criteria	RECIST 1.1	
Tumor ID: [TULNKID]	A10 or Sponsor-Defined CT	TU
Location: [TULOC]	▪ Breast *<LOC CT>*	TU
Method of Evaluation: [TUMETHOD]	▪ Clinical Exam ▪ CT Scan ▪ X-Ray *<METHOD CT>*	TU
Diameter: [TRTESTCD=DIAMETER][TRORRES]		TR
Diameter Unit: [TRORRESU]	**mm**	TR

CRF: Tumor Identification/Results Non-Target Lesions

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[TUTESTCD = TUMIDENT and TUORRES = NON-TARGET]

Response Criteria	RECIST 1.1	
Tumor ID: [TULNKID]	A10 or Sponsor-Defined CT	TU
Location: [TULOC]	▪ Breast *<LOC CT>*	TU
Method of Evaluation: [TUMETHOD]	▪ Clinical Exam ▪ CT Scan ▪ X-Ray *<METHOD CT>*	TU
Tumor State: [TRTESTCD=TUMSTATE][TRORRES]	▪ Present ▪ Absent ▪ Present without Unequicoval Progression ▪ Unequicoval Progression	TR

TU – Screening Visit

TULINKID	TUTEST	TUORRES	TULOC	TUMETHOD	VISIT
T01	Tumor Identification	TARGET	BREAST	CT SCAN	Screening
T02	Tumor Identification	TARGET	BREAST	CT SCAN	Screening
NT01	Tumor Identification	NON-TARGET	BREAST	CT SCAN	Screening

TR – Screening Visit

TRLNKID	TRLNKGRP	TRTEST	TRORRES	TRORRESU	VISIT
T01	A1	Diameter	20	mm	Screening
T02	A1	Diameter	15	mm	Screening
	A1	Sum of Diameter	35	mm	Screening
NT01	A1	Tumor State	PRESENT		Screening

TR – Week 6

TRLNKID	TRLNKGRP	TRTEST	TRORRES	TRORRESU	VISIT
	A1	Sum of Diameter	35	mm	Screening
T01	A2	Diameter	13	mm	Week 6
T02	A2	Diameter	17	mm	Week 6
	A2	Sum of Diameter	30	mm	Week 6
	A2	Percent Change from Baseline in Sum of Diameter	-14	%	Week 6
	A2	Percent Change from Nadir in Sum of Diameter	-14	%	Week 6
NT01	A2	Tumor State	PRESENT		Week 6

RS – Week 6

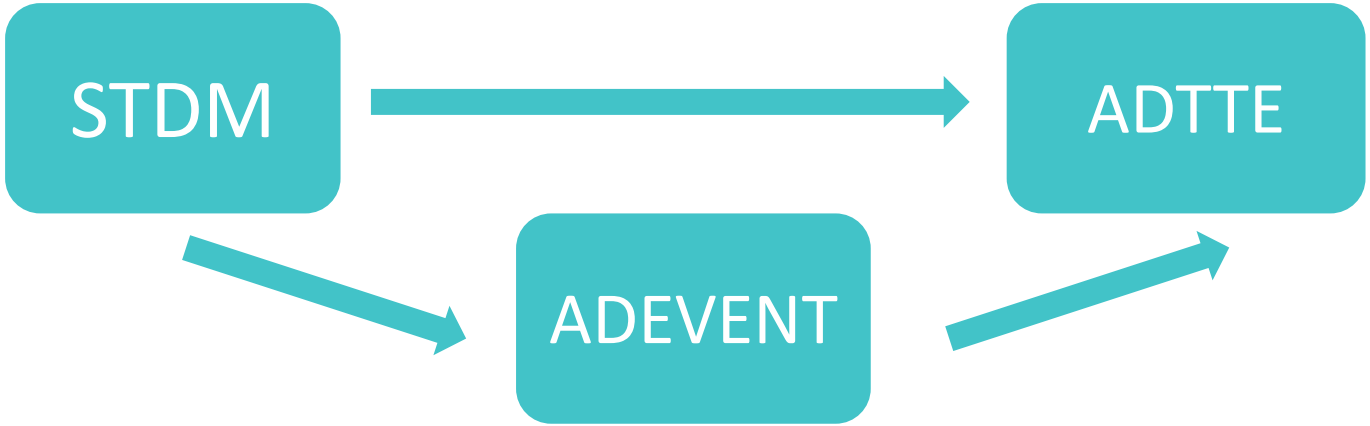
- Target Lesions: Change from BL / Nadir = -14%
- Non Target Lesions: Present

RSLNKGRP	RSTEST	RSCAT	RSORRES	VISIT
	Target Response	Recist 1.1	SD	Week 6
	Non-Target Response	Recist 1.1	Non-CR/Non-PD	Week 6
A2	Overall Response	Recist 1.1	SD	Week 6

Next Steps

ADaM: ADTTE

- Time to Event Endpoints:
  - Progression Free Survival, Overall Survival, Event Free Survival, Disease Free Survival, Duration of Response
- Tracebility back to SDTM data



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Thank you!

Any questions?

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